K083778

5. 510(k) SUMMARY

December 2, 2008

OWNER:

Baxter Healthcare Corporation
One Baxter Parkway
Deerfield, Illinois 60015

CONTACT PERSON:

Diane Rennpferd
Manager, Global Regulatory Affairs
1620 Waukegan Road
McGaw Park, IL 60085
Telephone: (847) 473-6293
Fax: (847) 785-5116

DEVICE NAME:

Trade name:
Xenium XPH

Table 5-1.
Product Codes for Xenium XPH

H25601A	Xenium XPH 110
H25602A	Xenium XPH 130
H25603A	Xenium XPH 150
H25604A	Xenium XPH 170
H25605A	Xenium XPH 190
H25606A	Xenium XPH 210

Common name: Dialyzer

Classification name: Dialyzer, high permeability with or without sealed dialysate

PREDICATE DEVICE:

Table 5-2.
Previous 510(k)s

Device	Company	Previous 510(k)	Clearance date
Xenium Dialyzer, Model 110, 130, 150, 170, 190, and 210	Baxter Healthcare	K062079	October 19, 2006

DESCRIPTION OF THE DEVICE:

Xenium XPH dialyzers are Polyethersulfone fiber dialyzers and will be labeled for single use only. The dialyzers are available in six (6) sizes, which differentiate by membrane surface area.

STATEMENT OF INTENDED USE:

Hemodialysis with Xenium XPH dialyzers is indicated for patients with acute or chronic renal failure when conservative therapy is judged to be inadequate. It also may be indicated in the treatment of patients intoxicated with poisons or drugs.

TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE:

The Xenium XPH is substantially equivalent to Baxter's current legally marketed Xenium Dialyzer, Model 110, 130, 150, 170, 190, and 210 cleared October 19, 2006 (K062079).

DISCUSSION OF NONCLINICAL TESTS:

Baxter Healthcare Corporation conducts risk analyses, per ISO 14971, and design verification tests based on the result of these analyses. All test results meet the acceptance criteria, and support that the devices are appropriately designed for their intended use.

CONCLUSION:

The Xenium XPH is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Diane Rennpferd
Manager, Global Regulatory Affairs
Baxter Health Care Corporation
Renal Division
1620 Waukegan Road
MCGAW PARK IL 60085

FEB 20 2009

Re: K083778
Trade/Device Name: Xenium XPH
Regulation Number: 21 CFR §876.5860
Regulation Name: High permeability hemodialysis system
Regulatory Class: II
Product Code: KDI
Dated: January 20, 2009
Received: January 23, 2009

Dear Ms. Rennpferd:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801; good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding os substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	(240) 276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	(240) 276-0115
21 CFR 892.xxx	(Radiology)	(240) 276-0120
Other		(240) 276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufactures, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry.suppot/index.html.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K083778

Device Name:
Xenium XPH

Indications for Use:

Hemodialysis with Xenium XPH dialyzers is indicated for patients with acute or chronic renal failure when conservative therapy is judged to be inadequate. It also may be indicated in the treatment of patients intoxicated with poisons or drugs.

Prescription Use __X__ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K083778